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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1681]

Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.'' This draft guidance updates a notice of availability entitled ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use'' published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In the draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified condition for use, and thus to obviate the risk of thyroid cancer in the event of a radiation emergency.

DATES: Submit written comments on the draft guidance by [*insert 30 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance

NAD 1

to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Executive Operations (HFD–06), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.''

The Federal Emergency Management Agency has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are expected to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, the DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

FDA is announcing the availability of a draft guidance that updates the notice of availability, ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use,'' published in the **Federal Register** of June 29, 1982 (47 FR 28158). In this draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thus to lessen the risk of thyroid cancer in the event of a radiation emergency. In this draft guidance, FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization (WHO),

as expressed in its ''Guidelines for Iodine Phrophylaxis Following Nuclear Accidents'' (1999), though they differ from those of the WHO in two areas.

First, for the sake of logistical simplicity, FDA recommends the 65-milligram (mg) dose of KI for all school-age children while allowing for the full adult dose of 130 mg in adolescents approaching adult size. WHO recommends 130 mg KI for adults and adolescents (over 12 years of age). Second, FDA recommends that KI prophylaxis in those under age 19 and in pregnant or lactating women be triggered at a predicted thyroid radioiodine exposure of 5 centiGray (cGy), while WHO establishes 1 cGy as the threshold for intervention. FDA has concluded from the Chernobyl data that the most reliable evidence demonstrates a significant increase in risk of childhood thyroid cancer at exposures of 5 cGy or greater.

The recommendations in the draft guidance were prepared by scientists from the Center for Drug Evaluation and Research and from the Center for Devices and Radiological Health of FDA in consultation with other governmental experts.

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on use of potassium iodide as a thyroid blocking agent in radiation emergencies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found

in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 26, 2000.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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